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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,794	09/01/2000	Meir S. Sacks	286262-00005	5973

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/653,794

Applicant(s)

Sacks

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 19, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The response filed on 3-19-02 is acknowledged.

Claims 1-25 are included in the prosecution. Claims 26-32 remain withdrawn as the non-elected claims without traverse.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 2. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duckett et al (6007,824) of record in combination with Hechtman (5,595,753) by itself or in further combination with Wysor (6,031,002).**

Duckett et al disclose compositions containing L-arginine and ginseng (antioxidant) for the treatment female sexual dysfunction. Duckett et al teach that the sexual stimulation causes local release of NO resulting in the smooth muscle relaxation and the increased blood flow. They further teach that L-arginine releases NO resulting in smooth muscle relaxation and increased inflow of blood (note the abstract, col. 1, line 12 through col. 2, line 46, col. 3, line 65 through col. 4, line 50 and claims). The mode of administration in Duckett however, is oral and not topical.

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Hechtman while disclosing formulations containing L-arginine for treating hemorrhoidal pain and sphincter and smooth muscle spasm teaches that the formulation is applied topically (note the abstract, columns 4-5 and claims). Hechtman further discloses the relationship between NO concentrations and the smooth muscle relaxation (note col. 1, line 56 through col. 2, line 27). According to Hechtman, a constitutive NO synthase enzyme is present in smooth muscle cells and that it is likely that L-arginine directly activates the system to cause the production of NO or related compound since the sphincter relaxation occurs within 10 minutes of application of this agonist (note col. 3, line 61 through col. 4, line 7).

Wysor while disclosing prostaglandin (vasodilator) formulations for enhancing female sexual response teaches that the formulations can be applied topically to the genitals and such a topical treatment is highly effective. Wysor further teaches the use of liposome formulations for the delivery of the composition (note the abstract, columns 1-3 and claims).

The application of L-arginine containing composition of Duckett topically would have been obvious to one of ordinary skill in the art since Hechtman teaches that the L-arginine is effective even when applied topically in the production of NO in smooth muscle cells. One of ordinary skill in the art would be motivated further to use Duckett's compositions topically since Wysor topical treatment for sexual dysfunction is highly effective.

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Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Duckett teaches that it is the combination of arginine, ginseng and Zizyphi fructus together that generates enough NO to have an effect on muscle relaxation and that according to Duckett, the NO generation from L-arginine alone would be insufficient to produce the desired result. Applicant further argues that according to the definition in the specification, the effective amount means "as being enough to bring about the desired amount of blood flow to the erectile tissue". These arguments are not found to be persuasive for the following reasons. First of all, 'the desired amount of blood flow' is not a quantitative definition and therefore, the increased amount of blood flow by arginine alone as taught in Duckett can be construed as the 'desired amount'. Furthermore, Duckett's findings are related to the oral administration and not topical. A careful evaluation of instant specification indicates that the "effective amounts" advocated by applicant are 1 mg up to 200 mg and the secondary reference of Hechtman which discloses topical administration of arginine clearly teaches 10 mg amounts. A careful examination of the specification also indicates that liposomal formulations of arginine esters were used and not free arginine and instant independent claim does not recite these requirements.

Applicant argues that Ginseng is not taught as an antioxidant by Duckett and that in instant invention, Ginseng is not an antioxidant. These arguments are not persuasive since the examiner has already cited Derwent abstract which teaches Ginseng as an antioxidant

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whether recognized by Duckett or not and instant independent claim does not state that Ginseng should not be the antioxidant.

Applicant argues that due to significant differences in oral administration versus topical administration, one skilled in the art would not combine the teachings of Hechtman and Duckett. The examiner disagrees because both references teach the same arginine and the secondary reference clearly shows the ability of arginine to penetrate the tissues when applied topically. Applicant argues that L-arginine may relieve hemorrhoidal pain and relax involuntary sphincter tension, does not mean it would enhance blood flow to erectile tissue. This argument is not found to be persuasive since one of ordinary skill in the art would infer two things from Hechtman: one- arginine is able to penetrate the tissue when applied topically; two - the sphincter tone moderator is nitric oxide (NO) which is similar to the one in the erectile tissue and therefore, one would expect a reasonable success.

Applicant argues that prostaglandins taught by Wysor have their half life too short for them to be effective in the manner of the present invention. This argument is not found to be persuasive since this reference is combined for its teachings of the topical application of liposomal active agents to enhance the female sexual response.

3. Claims 13-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duckett et al (6007,824) of record in combination with Hechtman (5,595,753) by itself or in further combination with Wyson (6,031,002) as set forth above, further in view of Chobanian et al (6,139,847).

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The teachings of Duckett, Hechtman and Wysor have been discussed above. What is lacking in these references is the explicit teachings of the inclusion of an antioxidant.

Although Duckett teaches the inclusion of ginseng, he neither teaches explicitly teach that this an antioxidant nor the inclusion of other antioxidants.

Chobanian et al while disclosing a treatment of fibrosis teach that antioxidants such as ascorbate, tocopherol and beta-carotene are NO catabolism inhibitors and advocates the use of the combination of NO stimulators (L-arginine) and NO catabolism inhibitors (note the abstract, col. 3, line 6 through col. 4, line 67, col. 5, line 40, Example 1 and claims).

The inclusion of an antioxidant in the compositions of Duckett would have been obvious to one of ordinary skill in the art, with the expectation of obtaining at least an additive effect, since Chobanian teaches that antioxidants are NO catabolism inhibitors and that they could be used in combination with NO stimulators.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to Duckett, Hechtman and Wysor have been addressed above. Applicant argues that Chobanian does not teach arginine as NO stimulators. This argument is not found to be persuasive since Chobanian provides motivation for one to combine an antioxidant with (NO catabolism inhibitor) with a NO stimulator; the primary reference clearly teaches that arginine is a NO stimulator.

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

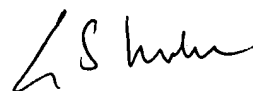
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

May 22, 2002